



California State Board of Pharmacy

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STATE AND CONSUMERS SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member

Ramón Castellblanch, Public Member

Deborah Veale, RPh

Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE

The Legislation and Regulation Committee did not meet during the last quarter.

PART II: LEGISLATION REPORT

a. Board Sponsored Legislation for 2012

ATTACHMENT 1

1. Omnibus Proposal to Amend Section 4209 of the Business and Professions Code Related to Intern Pharmacist Applicants and Applicants for the Pharmacist Licensure Examination

Existing law (B&PC § 4209) requires an intern pharmacist to complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. That section also specifies that an intern pharmacist shall submit proof of his or her experience on a board-approved affidavit, and sets criteria for submission.

Until 2011, the Board accepted intern hours earned in another state, if the hours were (1) verified by the state board of pharmacy in which the hours were earned; and (2) accepted board affidavits. However, upon further review of this policy, it was noted that acceptance of intern hour verification was contrary to the legal requirements established in Business and Professions Code section 4209(b). This resulted in a significant increase in staff resources required to complete the necessary license verifications, not only on the out-of-state intern applicants, but also for each pharmacist applying to take the California pharmacist licensure examination providing verification of the experience earned.

Attachment 1 contains language approved by the board in October 2011 to amend Business and Professions Code section 4209 which would provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned. The proposed language is being provided to the Senate Committee on Business, Professions and Economic Development for consideration in an Omnibus bill for this session.

2. Proposal to Enable the Board to Complete Discipline of a License That Becomes Cancelled Before Completion of the Investigation

FOR DISCUSSION AND POSSIBLE ACTION:

Staff is bringing the following legislative proposal to the board for consideration for board sponsorship.

Problem: Currently during board investigations, board inspectors typically interview licensees who are the subjects of investigations. In some cases, knowing that an investigation is underway and hoping to avoid future board discipline (in some cases to prevent other states from learning about board enforcement actions), these licensees will then not renew their licenses or ask that their licenses be cancelled. This occurs for both individual and site licensees. Additionally, for all license types except pharmacists, the law provides for cancellation of the license if it is not renewed within 60 days after expiration.

Once a license is cancelled, the board has no jurisdiction over the former licensee. Thus, the board cannot take any enforcement action against the individual or business to put serious violations on record.

To ensure the board can put the discipline on record, staff is suggesting an amendment to California Pharmacy Law that is similar to California accountancy law:

Board of Accountancy – Section 5109 of the Business and Professions Code

The expiration, cancellation, forfeiture, or suspension of a license, practice privilege, or other authority to practice public accountancy by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of or action or disciplinary proceeding against the licensee, or to render a decision suspending or revoking the license.

A draft that could accomplish this purpose is as follows:

Add Section 4300.1 to the Business and Professions Code

The expiration, cancellation, forfeiture or suspension of a board-issued license by operation of law or by order or decision of the board or courts of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of or action or disciplinary proceeding against the licensee, or to render a decision suspending or revoking the license.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

ATTACHMENT 2

1. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Board Position: Oppose (Ver. March 30, 2011)

Amended: January 17, 2012

Summary: AB 389 imposes specified requirements on providers of blood clotting products for home use for products used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. The board has expressed its opposition to the bill, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. Recent amendments (1/17/12) remove the definition for and references to "*home nursing services*," and make other technical changes.

The author's office has indicated they will be moving the measure forward this session. Attachment 2 contains the most recent amendment of the bill, the author's Fact Sheet, and the board's letter of opposition.

Status: Senate Third Reading (1/24/2012)

2. AB 1442 (Wieckowski) Using Common Carriers to Transport Pharmaceutical Waste

Introduced January 4, 2012

Summary: AB 1442 amends the Medical Waste Management Act to define, for purposes of the act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The measure excludes from the definition of "pharmaceutical waste" drugs that must be returned via a reverse distributor pursuant to section 4040.5 of the Business and Professions Code. Staff continues to review the provisions of the bill and may provide additional information at the Board Meeting.

Status: May be heard in committee February 4.

3. AB 377 (Solorio) Hospital Central Fill Pharmacies (2-Year Bill)

Amended: April 14, 2011

Board Position: Support if Amended (Ver. 4/14/11)

Summary: AB 377 provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified. The board has conveyed its concerns with the bill (to move the new centralized packaging provisions away from the definition of consolidated hospital license). The sponsor has agreed to make this amendment. The bill is moving forward in 2012.

Status: 2-Year Bill. In Senate Appropriations (8/15/11). No hearing date set as of 1/24/2012.

4. **AB 369 (Huffman) Health Care Coverage**

Introduced: February 14, 2011

Of interest. AB 369 addresses health care plan coverage of medications used in pain management therapies – it does not amend Pharmacy Law provisions. A copy of the bill is provided in **Attachment 2**.

Status: Assembly Second Reading File (1/19/2012)

Attachment 2 contains copies of the above bills and documents related to those measures.

4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

AMENDED IN SENATE JANUARY 17, 2012

AMENDED IN ASSEMBLY MARCH 30, 2011

AMENDED IN ASSEMBLY MARCH 15, 2011

AMENDED IN ASSEMBLY MARCH 7, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 389

Introduced by Assembly Member Mitchell

(Principal coauthor: Senator Pavley)

February 14, 2011

An act to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

LEGISLATIVE COUNSEL'S DIGEST

AB 389, as amended, Mitchell. Bleeding disorders.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Article 5 (commencing with Section 125286.10)
2 is added to Chapter 2 of Part 5 of Division 106 of the Health and
3 Safety Code, to read:

4
5 Article 5. Standards of Service for Providers of Blood Clotting
6 Products for Home Use Act
7

8 125286.10. This article shall be known, and may be cited, as
9 the Standards of Service for Providers of Blood Clotting Products
10 for Home Use Act.

11 125286.15. The Legislature hereby finds and declares all of
12 the following:

13 (a) Hemophilia is a rare, hereditary, bleeding disorder affecting
14 at least 4,000 persons in California and is a chronic, lifelong, and
15 incurable, but treatable, disease.

16 (b) Von Willebrand disease is a human bleeding disorder caused
17 by a hereditary deficiency or abnormality of the von Willebrand
18 factor in human blood, which is a protein that helps clot blood.
19 Von Willebrand disease is a chronic, lifelong, incurable, but
20 treatable, disease affecting at least 360,000 Californians.

21 (c) Until the 1970s, people with severe hemophilia suffered
22 from uncontrollable internal bleeding, crippling orthopedic
23 deformities, and a shortened lifespan. More recently, the production
24 of highly purified blood clotting factors has provided people with
25 hemophilia and other bleeding disorders the opportunity to lead
26 normal lives, free of pain and crippling arthritis.

27 (d) The preferred method of treatment of hemophilia today is
28 intravenous injection, or infusion, of prescription blood clotting
29 products several times per week, along with case management and
30 specialized medical care at a federally designated regional
31 hemophilia treatment center.

32 (e) Pharmacies and other entities specializing in the delivery of
33 blood clotting products and related equipment, supplies, and
34 services for home use form a growing enterprise in California.

35 (f) Timely access to federally designated regional hemophilia
36 centers and appropriate products and services in the home,
37 including infusion of blood clotting products and related
38 equipment, and supplies and services for persons with hemophilia

1 and other bleeding disorders, reduces mortality and bleeding-related
2 hospitalizations according to the federal Centers for Disease
3 Control and Prevention and the Medical and Scientific Advisory
4 Council of the National Hemophilia Foundation.

5 (g) Eligible persons with hemophilia or other bleeding disorders
6 may receive treatment through the Genetically Handicapped
7 Persons Program, the California Children's Services Program, and
8 the Medi-Cal program.

9 (h) For the benefit of persons with hemophilia or other bleeding
10 disorders, the purposes of this article are to do the following:

11 (1) Establish standards of service for entities that deliver blood
12 clotting products and related equipment, supplies, and services for
13 home use.

14 (2) Promote access to a full range of essential, cost-effective,
15 lifesaving, blood clotting products and related equipment, supplies,
16 and high-quality services for home use for persons with hemophilia
17 and other bleeding disorders.

18 125286.20. Unless the context otherwise requires, the following
19 definitions shall apply for purposes of this article:

20 (a) "Assay" means the amount of a particular constituent of a
21 mixture or of the biological or pharmacological potency of a drug.

22 (b) "Ancillary infusion equipment and supplies" means the
23 equipment and supplies required to infuse a blood clotting product
24 into a human vein, including, but not limited to, syringes, needles,
25 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,
26 tourniquets, medical tape, sharps or equivalent biohazard waste
27 containers, and cold compression packs.

28 (c) "Bleeding disorder" means a medical condition characterized
29 by a deficiency or absence of one or more essential blood clotting
30 proteins in the human blood, often called "factors," including all
31 forms of hemophilia and other bleeding disorders that, without
32 treatment, result in uncontrollable bleeding or abnormal blood
33 clotting.

34 (d) "Blood clotting product" means an intravenously
35 administered medicine manufactured from human plasma or
36 recombinant biotechnology techniques, approved for distribution
37 by the federal Food and Drug Administration, that is used for the
38 treatment and prevention of symptoms associated with bleeding
39 disorders. Blood clotting products include, but are not limited to,
40 ~~Factor VII, Factor~~ *factor VII*, *factor VIIa*, ~~Factor~~ *factor VIII*, and

Factor ~~factor~~ IX products, von Willebrand-Factor ~~factor~~ products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) “Emergency” means care as defined in Section 1317.1.

(f) “Hemophilia” means a human bleeding disorder caused by a hereditary deficiency of the ~~Factors~~ *factors* I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) “Hemophilia treatment center” means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

~~(h) “Home nursing services” means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.~~

~~(i)~~

(h) “Home use” means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

~~(j)~~

(i) “Patient” means a person needing a blood clotting product for home use.

~~(k)~~

(j) (1) “Provider of blood clotting products for home use” means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

~~(2) The providers described in this subdivision may also provide home nursing services for persons with bleeding disorders.~~

~~(3)~~

1 (2) The providers described in this subdivision shall include a
2 health care service plan and all its affiliated providers if the health
3 care service plan exclusively contracts with a single medical group
4 in a specified geographic area to provide professional services to
5 its enrollees.

6 125286.25. Each provider of blood clotting products for home
7 use shall meet all of the following requirements:

8 (a) Have sufficient knowledge and understanding of bleeding
9 disorders to accurately follow the instructions of the prescribing
10 physician and ensure high-quality service for the patient and the
11 medical and psychosocial management thereof, including, but not
12 limited to, home therapy.

13 (b) Have access to a provider with sufficient clinical experience
14 providing services to persons with bleeding disorders that enables
15 the provider to know when patients have an appropriate supply of
16 clotting factor on hand and about proper storage and refrigeration
17 of clotting factors.

18 (c) Maintain 24-hour on-call service seven days a week for
19 every day of the year, adequately screen telephone calls for
20 emergencies, acknowledge all telephone calls within one hour or
21 less, and have access to knowledgeable pharmacy staffing on call
22 24 hours a day, to initiate emergency requests for clotting factors.

23 (d) Have the ability to obtain all brands of blood clotting
24 products approved by the federal Food and Drug Administration
25 in multiple assay ranges (low, medium, and high, as applicable)
26 and vial sizes, including products manufactured from human
27 plasma and those manufactured with recombinant biotechnology
28 techniques, provided manufacturer supply exists and payer
29 authorization is obtained.

30 (e) Supply all necessary ancillary infusion equipment and
31 supplies with each prescription, as needed.

32 (f) Store and ship, or otherwise deliver, all blood clotting
33 products in conformity with all state and federally mandated
34 standards, including, but not limited to, the standards set forth in
35 the product's approved package insert (PI).

36 ~~(g) When home nursing services are necessary, as determined~~
37 ~~by the treating physician, provide these services either directly or~~
38 ~~through a qualified third party with experience in treating bleeding~~
39 ~~disorders and coordinate pharmacy services with the third party~~
40 ~~when one is used to provide home nursing services.~~

1 ~~(h)~~

2 (g) Upon receiving approved authorization for a nonemergency
3 prescription, provided manufacturer supply exists, ship the
4 prescribed blood clotting products and ancillary infusion equipment
5 and supplies to the patient within two business days or less for
6 established and new patients.

7 ~~(i)~~

8 (h) Upon receiving approved authorization to dispense a
9 prescription for an emergency situation, provided manufacturer
10 supply exists, deliver prescribed blood products, ancillary infusion
11 equipment and supplies, ~~medications, and home nursing services~~
12 *and medications* to the patient within 12 hours for patients living
13 within 100 miles of a major metropolitan airport, and within one
14 day for patients living more than 100 miles from a major
15 metropolitan airport.

16 ~~(j)~~

17 (i) Provide patients who have ordered their products with a
18 designated contact telephone number for reporting problems with
19 a delivery and respond to these calls within a reasonable time
20 period.

21 ~~(k)~~

22 (j) Provide patients with notification of Class 1 and Class 2
23 recalls and withdrawals of blood clotting products and ancillary
24 infusion equipment within 24 hours of the provider of blood
25 clotting products for home use receiving notification and participate
26 in the National Patient Notification System for blood clotting
27 product recalls.

28 ~~(l)~~

29 (k) Provide language interpretive services over the telephone
30 or in person, as needed by the patient.

31 ~~(m)~~

32 (l) Have a detailed plan for meeting the requirements of this
33 article in the event of a natural or manmade disaster or other
34 disruption of normal business operations.

35 ~~(n)~~

36 (m) Provide appropriate and necessary recordkeeping and
37 documentation as required by state and federal law and retain
38 copies of the patient's prescriptions.

39 ~~(o)~~

1 (n) Comply with the privacy and confidentiality requirements
2 of the federal Health Insurance Portability and Accountability Act
3 of 1996 (HIPAA).

4 125286.30. The California State Board of Pharmacy shall
5 administer and enforce this article.

6 125286.35. Nothing in this article shall apply to either hospital
7 pharmacies or health system pharmacies that dispense blood
8 clotting products due only to emergency, urgent care, or inpatient
9 encounters, or if an inpatient is discharged with a supply of blood
10 clotting products for home use.

O

Assembly Bill 389

Hemophilia – Standards for Clotting Factor in Home Setting

ISSUE

For people with hemophilia, and other bleeding disorders, it is often necessary that they receive intravenous injection or infusion of prescription blood clotting products several times a week. Most patients use these products at home.

Currently, pharmacies that provide clotting factor to patients on state programs: Medi-Cal, CA Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) must comply with standards that are included in written contracts with the State.

Because these standards are not established for pharmacy providers with patients on private insurance, patients have endured some difficulties in receiving their products. For example, clotting factor has been left on patients' front porches resulting in spoilage due to the heat. Clotting factor is lifesaving for patients and needs to be available on a regular and emergency basis. Additionally, spoilage causes financial hardship as it is an expensive biological product.

BACKGROUND

Currently, there are no standards in State law that governs the proper storage and delivery of blood clotting products for private patients.

THIS BILL

AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, and other bleeding disorders.

SUMMARY

AB 389 creates a uniform standard for both public and private pay patients who receive clotting factors. This bill will assure that both public and private pay patients receive the same standard of care.

SUPPORT

- Hemophilia Council of CA (sponsor)
- Accredo Health Group Inc.
- Baxter Healthcare
- California Academy of Family Physicians
- California Medical Association
- California Pharmacists Association
- California Society of Health System Pharmacists
- Community Healthcare Services
- CSL Behring
- DLA Piper
- DRG Pharmacy LLC
- Federal Hemophilia Treatment Centers Region XI
- Grifols, Inc.
- Hemophilia Foundation of Northern California
- Herndon Pharmacy
- Meyer Family Cellars
- National Cornerstone Healthcare Services, Inc.
- Pfizer
- Red Chip Enterprises
- Talecris Biotherapeutics
- UC Davis Medical Center
- Walgreens

OPPOSITION

None

VOTES

- | | |
|-------------------------|------|
| ▪ Senate Appropriations | 28-8 |
| ▪ Senate Health | 8-0 |

- Assembly Floor 78-0
- Assembly Appropriations 12-3
- Assembly Health 15-3
- Assembly BP &CP 9-0

FOR MORE INFORMATION

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

August 18, 2011

The Honorable Holly Mitchell
Member, California State Assembly
State Capitol, Room 2176
Sacramento, CA 95816

RE: AB 389

Dear Assembly Member Mitchell:

I regret to advise you that the Board of Pharmacy has taken an oppose position on your AB 389. This bill would codify a number of current standards of practice for pharmacies that dispense blood clotting products to patients with bleeding disorders. I recognize the lateness of notification, and I apologize for the timing.

The board believes that pharmacies that service patients with bleeding disorders are typically specialized in providing such care, have close relationships with their patients and comply with all of the standards in this bill, with the exception of arranging for nursing services (which is usually outside the realm of pharmacy). We are not aware of any problems in the care provided by pharmacies to patients with bleeding disorders and cannot recall a situation where the board has received a complaint in this area.

As such, without a compelling need to establish specially codified provisions for a medical condition, the board is hesitant to endorse such requirements because they seem unnecessary and could lead to a plethora of additional specialized requirements in law for patients with other conditions. The result would be a more complex series of provisions that could actually impair patient care and compliance with the already extensive provisions in place to regulate pharmacy care.

I had the pleasure of meeting with Tiffany Jones of your staff and the sponsors of this bill early this summer, and I strongly encouraged them to file complaints with the board when they question the quality of pharmacy care or products provided to them. Without such complaints, the board finds it difficult to fulfill its consumer protection mandate. They agreed to do so in the future, and this will aid us in identifying and resolving issues for these patients should problems arise.

Please do not hesitate to contact me at (916) 574-7911 with questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold".

VIRGINIA HEROLD
Executive Officer

ASSEMBLY BILL

No. 1442

Introduced by Assembly Member Wieckowski

January 4, 2012

An act to amend Sections 117935, 117945, 117960, 118000, and 118165 of, and to add Sections 117637, 117748, and 118032 to, the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as introduced, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would authorize a medical waste generator or parent organization that employs health care professionals who generate pharmaceuticals to apply to the enforcement agency for a pharmaceutical waste hauling exemption if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 117637 is added to the Health and Safety
2 Code, to read:

3 117637. “Common carrier” means either of the following:

4 (a) A person or company that has a United States Department
5 of Transportation number issued by the Federal Motor Carrier
6 Safety Administration and is registered with the Federal Motor
7 Carrier Safety Administration as an interstate motor carrier and
8 for-hire property carrier.

9 (b) A person or company that has a motor carrier of property
10 permit issued by the Department of Motor Vehicles pursuant to
11 the Motor Carriers of Property Permit Act (Division 14.85
12 commencing with Section 34600) of the Vehicle Code) and a
13 carrier identification number issued by the Department of the
14 California Highway Patrol pursuant to Section 34507.5 of the
15 Vehicle Code.

16 SEC. 2. Section 117748 is added to the Health and Safety Code,
17 to read:

18 117748. (a) “Pharmaceutical waste” means any pharmaceutical,
19 as defined in Section 117747, that for any reason may no longer
20 be sold or dispensed for use as a drug.

21 (b) For purposes of this part, “pharmaceutical waste” does not
22 include any pharmaceutical that still has potential value to the
23 generator because it is being returned to a reverse distributor, as
24 defined in Section 4040.5 of the Business and Professions Code,
25 that is licensed both as a wholesaler of dangerous drugs by the
26 California State Board of Pharmacy pursuant to Section 4160 of
27 the Business and Professions Code and as a permitted transfer
28 station pursuant to Section 117775, for possible manufacturer
29 credit.

SEC. 3. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

- (a) The name of the person.
- (b) The business address of the person.
- (c) The type of business.
- (d) The types, and the estimated average monthly quantity, of medical waste generated.
- (e) The type of treatment used onsite.
- (f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~, the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, *and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032.*
- (g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.
- (h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.
- (i) A statement certifying that the information provided is complete and accurate.

SEC. 4. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

1 (a) An information document stating how the generator contains,
2 stores, treats, and disposes of any medical waste generated through
3 any act or process of the generator.

4 (b) Records of any medical waste transported offsite for
5 treatment and disposal, including the quantity of waste transported,
6 the date transported, ~~and~~ the name of the registered hazardous
7 waste hauler or individual hauling the waste pursuant to Section
8 118030, *and, if applicable, the name of the common carrier*
9 *transporting pharmaceutical waste pursuant to Section 118032.*

10 The small quantity generator shall maintain these records for not
11 less than two years.

12 SEC. 5. Section 117960 of the Health and Safety Code is
13 amended to read:

14 117960. Any large quantity generator required to register with
15 the enforcement agency pursuant to Section 117950 shall file with
16 the enforcement agency a medical waste management plan, on
17 forms prescribed by the enforcement agency containing, but not
18 limited to, all of the following:

19 (a) The name of the person.

20 (b) The business address of the person.

21 (c) The type of business.

22 (d) The types, and the estimated average monthly quantity, of
23 medical waste generated.

24 (e) The type of treatment used onsite, if applicable. For
25 generators with onsite medical waste treatment facilities, including
26 incinerators or steam sterilizers or other treatment facilities as
27 determined by the enforcement agency, the treatment capacity of
28 the onsite treatment facility.

29 (f) The name and business address of the registered hazardous
30 waste hauler used by the generator to have untreated medical waste
31 removed for treatment, if applicable, *and, if applicable, the name*
32 *and business address of the common carrier transporting*
33 *pharmaceutical waste pursuant to Section 118032.*

34 (g) The name and business address of the registered hazardous
35 waste hauler service provided by the building management to
36 which the building tenants may subscribe or are required by the
37 building management to subscribe, if applicable.

38 (h) The name and business address of the offsite medical waste
39 treatment facility to which the medical waste is being hauled, if
40 applicable.

1 (i) An emergency action plan complying with regulations
2 adopted by the department.

3 (j) A statement certifying that the information provided is
4 complete and accurate.

5 SEC. 6. Section 118000 of the Health and Safety Code is
6 amended to read:

7 118000. (a) Except as otherwise exempted pursuant to Section
8 118030 *or* 118032, all medical waste transported to an offsite
9 medical waste treatment facility shall be transported in accordance
10 with this chapter by a registered hazardous waste transporter issued
11 a registration certificate pursuant to Chapter 6 (commencing with
12 Section 118025) and Article 6.5 (commencing with Section
13 25167.1) of Chapter 6.5 of Division 20. A hazardous waste
14 transporter transporting medical waste shall have a copy of the
15 transporter's valid hazardous waste transporter registration
16 certificate in the transporter's possession while transporting
17 medical waste. The transporter shall show the certificate, upon
18 demand, to any enforcement agency personnel or authorized
19 employee of the Department of the California Highway Patrol.

20 (b) Except for small quantity generators transporting medical
21 waste pursuant to Section 118030 *or small quantity generators or*
22 *common carriers transporting pharmaceutical waste pursuant to*
23 *Section 118032*, medical waste shall be transported to a permitted
24 offsite medical waste treatment facility or a permitted transfer
25 station in leak-resistant and fully enclosed rigid secondary
26 containers that are then loaded into an enclosed cargo body.

27 (c) A person shall not transport medical waste in the same
28 vehicle with other waste unless the medical waste is separately
29 contained in rigid containers or kept separate by barriers from
30 other waste, or unless all of the waste is to be handled as medical
31 waste in accordance with this part.

32 (d) Medical waste shall only be transported to a permitted
33 medical waste treatment facility, or to a transfer station or another
34 registered generator for the purpose of consolidation before
35 treatment and disposal, pursuant to this part.

36 (e) Facilities for the transfer of medical waste shall be annually
37 inspected and issued permits in accordance with the regulations
38 adopted pursuant to this part.

39 (f) Any persons manually loading or unloading containers of
40 medical waste shall be provided by their employer at the beginning

1 of each shift with, and shall be required to wear, clean and
2 protective gloves and coveralls, changeable lab coats, or other
3 protective clothing. The department may require, by regulation,
4 other protective devices appropriate to the type of medical waste
5 being handled.

6 SEC. 7. Section 118032 is added to the Health and Safety Code,
7 to read:

8 118032. (a) A medical waste generator or parent organization
9 that employs health care professionals who generate pharmaceutical
10 waste may apply to the enforcement agency for a pharmaceutical
11 waste hauling exemption if the generator, health care professional,
12 or parent organization meets all of the following requirements:

13 (1) The generator or parent organization has on file one of the
14 following:

15 (A) If the generator or parent organization is a small quantity
16 generator required to register pursuant to Chapter 4 (commencing
17 with Section 117915), a medical waste management plan prepared
18 pursuant to Section 117935.

19 (B) If the generator or parent organization is a small quantity
20 generator not required to register pursuant to Chapter 4
21 (commencing with Section 117915), the information document
22 maintained pursuant to subdivision (a) of Section 117945.

23 (C) If the generator or parent organization is a large quantity
24 generator, a medical waste management plan prepared pursuant
25 to Section 117960.

26 (2) The generator or health care professional who generated the
27 pharmaceutical waste transports the pharmaceutical waste himself
28 or herself, or directs a member of his or her staff to transport the
29 pharmaceutical waste to a parent organization or another health
30 care facility for the purpose of consolidation before treatment and
31 disposal, or contracts with a common carrier to transport the
32 pharmaceutical waste to a permitted medical waste treatment
33 facility or transfer station.

34 (3) Except as provided in paragraph (4), the generator maintains
35 a tracking document, as specified in Section 118040.

36 (4) (A) Notwithstanding paragraph (3), if a health care
37 professional who generates pharmaceutical waste returns the
38 pharmaceutical waste to the parent organization, a single-page
39 form or multiple entry log may be substituted for the tracking

1 document, if the form or log contains all of the following
2 information:

3 (i) The name of the person transporting the pharmaceutical
4 waste.

5 (ii) The number of containers of pharmaceutical waste. This
6 clause does not require any generator to maintain a separate
7 medical waste container for every patient or to maintain records
8 as to the specified source of the pharmaceutical waste in any
9 container.

10 (iii) The date that the pharmaceutical waste was returned.

11 (B) This paragraph does not prohibit the use of a single
12 document to verify the return of more than one container to a parent
13 organization or another health care facility for the purpose of
14 consolidation before treatment and disposal over a period of time,
15 if the form or log is maintained in the files of the parent
16 organization or another health care facility that receives the waste
17 once the form or log is completed.

18 SEC. 8. Section 118165 of the Health and Safety Code is
19 amended to read:

20 118165. On and after April 1, 1991, all persons operating a
21 medical waste treatment facility shall maintain individual records
22 for a period of three years and shall report or submit to the
23 enforcement agency upon request, all of the following information:

24 (a) The type of treatment facility and its capacity.

25 (b) All treatment facility operating records.

26 (c) Copies of the tracking documents for all medical waste it
27 receives for treatment from offsite generators ~~or from~~, hazardous
28 waste haulers, *or, pursuant to Section 118032, common carriers.*

29 SEC. 9. No reimbursement is required by this act pursuant to
30 Section 6 of Article XIII B of the California Constitution because
31 the only costs that may be incurred by a local agency or school
32 district will be incurred because this act creates a new crime or
33 infraction, eliminates a crime or infraction, or changes the penalty
34 for a crime or infraction, within the meaning of Section 17556 of
35 the Government Code, or changes the definition of a crime within
36 the meaning of Section 6 of Article XIII B of the California
37 Constitution.

AMENDED IN ASSEMBLY APRIL 14, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license, *but would impose limitations on the services provided by a centralized hospital pharmacy*. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4029 of the Business and Professions
- 2 Code is amended to read:
- 3 4029. (a) "Hospital pharmacy" means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets

1 all of the requirements of this chapter and the rules and regulations
2 of the board.

3 (b) A hospital pharmacy also includes a pharmacy, licensed by
4 the board, that may be located outside of the hospital, in either
5 another physical plant on the same premises or on a separate
6 premises, located within a ~~100-mile~~ 100-mile radius of the hospital,
7 that is regulated under a hospital's license. *A centralized hospital*
8 *pharmacy may only provide pharmaceutical services to its own*
9 *patients who are either admitted or registered patients of a hospital*
10 *within the same health care system.* Nothing in this subdivision
11 shall be construed to restrict or expand the services that a hospital
12 pharmacy may provide.

13 (c) Any unit-dose medication produced by a hospital pharmacy
14 under common ownership, as described in Section 4033, shall be
15 barcoded to be readable at the patient's bedside.

16 (d) A hospital pharmacy may prepare and store a limited quantity
17 of unit-dose medications in advance of receipt of a patient-specific
18 prescription in a quantity as is necessary to ensure continuity of
19 care for an identified population of patients of the hospital based
20 on a documented history of prescriptions for that patient population.

21 (e) Nothing in this section shall limit the obligation of a hospital
22 pharmacy, hospital, or pharmacist to comply with all applicable
23 federal and state laws.

24 SEC. 2. Section 4033 of the Business and Professions Code is
25 amended to read:

26 4033. (a) (1) "Manufacturer" means and includes every person
27 who prepares, derives, produces, compounds, or repackages any
28 drug or device except a pharmacy that manufactures on the
29 immediate premises where the drug or device is sold to the ultimate
30 consumer.

31 (2) Notwithstanding paragraph (1), "manufacturer" shall not
32 mean a pharmacy compounding or repackaging a drug for
33 parenteral therapy or oral therapy in a hospital for delivery to
34 another pharmacy or hospital under common ownership for the
35 purpose of dispensing or administering the drug, pursuant to a
36 prescription or order, to the patient or patients named in the
37 prescription or order. A pharmacy compounding or repackaging
38 a drug as described in this paragraph shall notify the board in
39 writing of the location where the compounding or repackaging is
40 being performed within 30 days of initiating the compounding or

1 repackaging. The pharmacy shall report any change in that
2 information to the board in writing within 30 days of the change.

3 (3) Notwithstanding paragraph (1), “manufacturer” shall not
4 mean a pharmacy that, at a patient’s request, repackages a drug
5 previously dispensed to the patient, or to the patient’s agent,
6 pursuant to a prescription.

7 (b) Notwithstanding subdivision (a), as used in Sections 4034,
8 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”
9 means a person who prepares, derives, manufactures, produces,
10 or repackages a dangerous drug, as defined in Section 4022, device,
11 or cosmetic. Manufacturer also means the holder or holders of a
12 New Drug Application (NDA), an Abbreviated New Drug
13 Application (ANDA), or a Biologics License Application (BLA),
14 provided that such application has been approved; a manufacturer’s
15 third-party logistics provider; a private label distributor (including
16 colicensed partners) for whom the private label distributor’s
17 prescription drugs are originally manufactured and labeled for the
18 distributor and have not been repackaged; or the distributor agent
19 for the manufacturer, contract manufacturer, or private label
20 distributor, whether the establishment is a member of the
21 manufacturer’s affiliated group (regardless of whether the member
22 takes title to the drug) or is a contract distributor site.

23 SEC. 3. No reimbursement is required by this act pursuant to
24 Section 6 of Article XIII B of the California Constitution because
25 the only costs that may be incurred by a local agency or school
26 district will be incurred because this act creates a new crime or
27 infraction, eliminates a crime or infraction, or changes the penalty
28 for a crime or infraction, within the meaning of Section 17556 of
29 the Government Code, or changes the definition of a crime within
30 the meaning of Section 6 of Article XIII B of the California
31 Constitution.

ASSEMBLY BILL

No. 369

Introduced by Assembly Member Huffman
(Coauthors: Assembly Members Beall and Feuer)
(Coauthor: Senator Pavley)

February 14, 2011

An act to add Section 1367.243 to the Health and Safety Code, and to add Section 10123.192 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 369, as introduced, Huffman. Health care coverage: prescription drugs.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Commonly referred to as utilization review, existing law governs the procedures that apply to every health care service plan and health insurer that prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based on medical necessity, requests by providers prior to, retrospectively, or concurrent with, the provision of health care services to enrollees or insureds, as specified.

Existing law also imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, requiring a health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers, as described, may obtain authorization for a medically

necessary nonformulary prescription drug, according to certain procedures. Existing law also requires every health care service plan that provides prescription drug benefits that maintains one or more drug formularies to provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary.

This bill would impose specified requirements on health care service plans or health insurers that restrict medications for the treatment of pain pursuant to step therapy or fail first protocol. The bill would authorize the duration of any step therapy or fail first protocol to be determined by the prescribing physician and would prohibit a health care service plan or health insurer from requiring that a patient try and fail on more than two pain medications before allowing the patient access to other pain medication prescribed by the physician, as specified.

Because a willful violation of the bill's provisions relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1367.243 is added to the Health and
- 2 Safety Code, to read:
- 3 1367.243. (a) Notwithstanding any other provision of law, a
- 4 health care service plan that restricts medications for the treatment
- 5 of pain pursuant to step therapy or fail first protocol shall be subject
- 6 to the requirements of this section.
- 7 (b) The duration of any step therapy or fail first protocol shall
- 8 be determined by the prescribing physician.
- 9 (c) The health care service plan shall not require a patient to try
- 10 and fail on more than two pain medications before allowing the
- 11 patient access to the pain medication, or generically equivalent
- 12 drug, prescribed by the physician.
- 13 (d) Once a patient has tried and failed on two pain medications,
- 14 prior authorization is no longer required and the physician may

1 write the prescription for the appropriate pain medication. A note
2 in the patient's chart that a patient has tried and failed on the health
3 care service plan's step therapy or fail first protocol shall suffice
4 as prior authorization from the plan.

5 (e) When the physician notes on the prescription that the health
6 care service plan's step therapy or fail first protocols have been
7 met, a pharmacist may process the prescription without additional
8 communication with the plan.

9 (f) For the purposes of this section, "generically equivalent
10 drug" means drug products with the same active chemical
11 ingredients of the same strength, quantity, and dosage form, and
12 of the same generic drug name, as determined by the United States
13 Adopted Names and accepted by the federal Food and Drug
14 Administration, as those drug products having the same chemical
15 ingredient.

16 (g) This section does not prohibit a health care service plan from
17 charging a subscriber or enrollee a copayment or a deductible for
18 prescription drug benefits or from setting forth, by contract,
19 limitations on maximum coverage of prescription drug benefits,
20 provided that the copayments, deductibles, or limitations are
21 reported to, and held unobjectionable by, the director and
22 communicated to the subscriber or enrollee pursuant to the
23 disclosure provisions of Section 1363.

24 (h) Nothing in this section shall be construed to require coverage
25 of prescription drugs not in a plan's drug formulary or to prohibit
26 generically equivalent drugs or generic drug substitutions as
27 authorized by Section 4073 of the Business and Professions Code.

28 SEC. 2. Section 10123.192 is added to the Insurance Code, to
29 read:

30 10123.192. (a) Notwithstanding any other provision of law,
31 a health insurer that restricts medications for the treatment of pain
32 pursuant to step therapy or fail first protocol shall be subject to the
33 requirements of this section.

34 (b) The duration of any step therapy or fail first protocol shall
35 be determined by the prescribing physician.

36 (c) The health insurer shall not require a patient to try and fail
37 on more than two pain medications before allowing the patient
38 access to the pain medication, or generically equivalent drug,
39 prescribed by the physician.

1 (d) Once a patient has tried and failed on two pain medications,
2 prior authorization is no longer required and the physician may
3 write the prescription for the appropriate pain medication. A note
4 in the patient's chart that a patient has tried and failed on the health
5 insurer's step therapy or fail first protocol shall suffice as prior
6 authorization from the insurer.

7 (e) When the physician notes on the prescription that the health
8 insurer's step therapy or fail first protocols have been met, a
9 pharmacist may process the prescription without additional
10 communication with the insurer.

11 (f) For the purposes of this section, "generically equivalent
12 drug" means drug products with the same active chemical
13 ingredients of the same strength, quantity, and dosage form, and
14 of the same generic drug name, as determined by the United States
15 Adopted Names and accepted by the federal Food and Drug
16 Administration, as those drug products having the same chemical
17 ingredient.

18 (g) This section does not prohibit a health insurer from charging
19 an insured or policyholder a copayment or a deductible for
20 prescription drug benefits or from setting forth, by contract,
21 limitations on maximum coverage of prescription drug benefits,
22 provided that the copayments, deductibles, or limitations are
23 reported to, and held unobjectionable by, the commissioner and
24 communicated to the insured or policyholder pursuant to the
25 disclosure provisions of Section 10603.

26 (h) Nothing in this section shall be construed to require coverage
27 of prescription drugs not in an insurer's drug formulary or to
28 prohibit generically equivalent drugs or generic drug substitutions
29 as authorized by Section 4073 of the Business and Professions
30 Code.

31 SEC. 3. No reimbursement is required by this act pursuant to
32 Section 6 of Article XIII B of the California Constitution because
33 the only costs that may be incurred by a local agency or school
34 district will be incurred because this act creates a new crime or
35 infraction, eliminates a crime or infraction, or changes the penalty
36 for a crime or infraction, within the meaning of Section 17556 of
37 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<p>1. Secure extension of board's sunset date.</p> <p><i>1st Qtr 06/07: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</i></p> <p><i>4th Qtr 06/07: SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</i></p> <p><i>1st Qtr 08/09: SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</i></p> <p><i>Governor signs SB 963 (Chapter 385, Statutes of 2008)</i></p> <p><i>1st Qtr 09/10: Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.</i></p> <p><i>2nd Qtr 09/10: Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.</i></p> <p><i>3rd Qtr 09/10: Sunset bills introduced</i></p> <p><i>AB 1659 (Huber) – State Government, Agency Repeals</i></p> <p><i>AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection</i></p> <p><i>SB 954 (Harmon) – Legislative Procedure, Committee Referrals</i></p> <p><i>SB 1171 (Negrete McLeod) – Regulatory Boards, Operations</i></p> <p><i>4th Qtr 09/10: SB 954 (Harmon) – Bill is dead (Failed deadline)</i></p> <p><i>SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)</i></p> <p><i>1st Qtr 10/11: Governor signs AB 1659 (Chapter 666, Statutes of 2010)</i></p> <p><i>Governor signs AB 2130 (Chapter 670, Statutes of 2010)</i></p> <p><i>Nov 2011: Board submits Sunset Report to Senate Committee on Business, Professions and Economic Development</i></p>

2. Sponsor legislation to update pharmacy law.

Enacted - 1st Qtr. 08/09: SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions

Oct. 2007: Board sponsors omnibus provisions for 2008. Four types of changes are discussed.

(1) Changes specific to the PIC and DRC requirements

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
- Section 4036.5 – Pharmacist-in-Charge
- Section 4161 – Nonresident wholesaler
- Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
- Section 4329 – Nonpharmacists; Prohibited Acts
- Section 4330 – Proprietors; Prohibited Acts

(2) Changes to allow for the use of mobile pharmacies

- Section 4062 – Furnishing Dangerous Drugs During an Emergency.
- Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.

(3) General changes

- Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.
- Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.
- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.
- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) Changes based on recodification of Business and Professions

Code section 4052

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

	<p>Jan. 2008: <i>Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.</i></p> <p><i>Board approved language for omnibus bill.</i></p> <p>April 2008: <i>Some provisions of omnibus bill removed:</i></p> <ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i> <p>Oct. 2008: <i>Governor vetoes SB 1779</i></p> <p>1st Qtr 08/09: <i>Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change: (Included in SB 819)</i></p> <p><i>(1) Changes specific to the PIC and DRC requirements</i></p> <ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i> <p><i>(2) Changes to allow for the use of mobile pharmacies</i></p> <ul style="list-style-type: none"> • <i>Section 4062 – Furnishing Dangerous Drugs During an Emergency.</i> • <i>Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.</i> <p><i>(3) General changes</i></p> <ul style="list-style-type: none"> • <i>Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.</i> • <i>Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory</i> • <i>Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.</i> • <i>Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.</i> <p><i>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</i></p>
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	<p>(4) <i>Changes based on recodification of Business and Professions Code section 4052</i></p> <ul style="list-style-type: none"> • <i>Section 733 – Dispensing Prescription Drugs and Devices</i> • <i>Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities</i> • <i>Section 4040 – Prescription; Content Requirements</i> • <i>Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist</i> • <i>Section 4060 – Controlled Substance – Prescription Required, Exceptions</i> • <i>Section 4076 – Prescription Container – Requirements for Labeling</i> • <i>Section 4111 – Restrictions on Prescriber Ownership</i> • <i>Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner</i> • <i>H&SC 11150 – Persons Authorized to Write or Issue a Prescription</i> <p>1st Qtr 08/09: <i>Board seeks to introduce additional changes: (Included in SB 821)</i></p> <ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i> <p><i>New Provisions</i></p> <ul style="list-style-type: none"> • <i>4200.1 – Pharmacist Examination; Remedial Education</i> • <i>4112 – Non-resident Pharmacy: Registration Required</i> • <i>4146 – Return and Disposal of Sharps</i> • <i>4013 – Subscriber Alert</i> <p>3rd Qtr 08/09: <i>SB 821 introduced</i></p>
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2nd Qtr 09/10: Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.

3rd Qtr 09/10: Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.

Omnibus Proposal #1:

- (1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)
 - §4017 – Authorized Officers of the Law
 - §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
 - §4028 – Definition of Licensed Hospital
 - §4037 – Definition of Pharmacy
 - §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
 - §4072 – Oral or Electronic Transmission of Prescription – Health Care Facility
 - §4101 – Pharmacist-in-Charge, Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board
Prescription: Exceptions.
 - §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
 - §4127.1 – License to Compound Injectable Sterile Drug Products Required
 - §4169 – Prohibited Acts (also, strike operative date of 2008)
 - §4181 – License Requirements; Policies and Procedures; Who May Dispense
 - §4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs
- (2) Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
 - §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- (3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)
 - §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
 - §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

- (1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative-in-Charge
- (2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)
- (3) Add §4362 – Pharmacists Recovery Program

3rd Qtr 09/10: SB 1489 introduced (Senate Business, Professions, and Economic Development Committee). Includes proposals #1 and #2, with the exception of §4362.

	<p>4th Qtr 09/10: Board establishes support position of SB 1489. SB 1489 is amended to modify §4013 – Subscriber Alert provisions for an owner of two or more pharmacies. SB 1489 is amended to modify §4076.5 – Patient-Centered Prescription Labels to authorize the board to exempt long-term health care facilities from regulations.</p> <p>1st Qtr 10/11: Governor signs SB 1489 (Chapter 653, Statutes of 2010).</p> <p>2nd Qtr 10/11: Board seeks to pursue omnibus provisions Section 4200 – Remove obsolete reference to prior pharmacist examination Staff provides language to Senate Committee on Business, Professions and Economic Development for inclusion in an omnibus bill.</p> <p>3rd Qtr 10/11: Staff provides language to Senate Business Professions and Economic Development for inclusion in Omnibus Bill. SB 943 is introduced. Contains amendments to section 4200.</p> <p>1st Qtr 11/12: Governor signs SB 943 (Chapter 350, Statutes of 2011).</p> <p>2nd Qtr 11/12: Board seeks to pursue omnibus provision Section 4209 – To allow for the reporting of intern hours to the Board of Pharmacy by other state boards of pharmacy</p> <p>3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408). Sep. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.</p> <p>4. Secure statutory standards for pharmacies that compound medications (AB 595). Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future. Aug. 2008: Regulatory effort initiated. (See Objective 3.2, Task 12) Oct. 2009: Board approves regulatory language for Initial Notice. Jan. 2010: Office of Administrative Law approves regulation. July 2010: Regulation effective.</p> <p>5. Secure implementation of e-pedigrees on prescription drugs dispensed in California. Sep. 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations. Sep. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.</p>
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	<p>6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.</p> <p>Oct. 2007: Governor signs the following: <i>AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.</i> <i>SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.</i> <i>SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.</i></p> <p> Governor vetoes the following: <i>AB 249 (Eng) Healing Arts: Settlement Agreements.</i> <i>AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.</i> <i>AB 1025 (Bass) Professions and Vocations: Denial of Licensure.</i> <i>SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</i></p> <p>Oct. 2008: Governor signs the following: <i>AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks</i> <i>SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review</i></p> <p> Governor vetoes the following: <i>AB 501 (Swanson) Pharmaceutical Devices</i> <i>AB 865 (Davis) State Agencies</i> <i>AB1574 (Plescia) Surgical Clinics: Licensure</i></p> <p>Jan. 2009: <i>Legislation introduced affecting Pharmacy law:</i> (New Session) <i>AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.</i> <i>SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.</i></p>
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	<p>4th Qtr 08/09: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHDPD) AB 1370 (Solorio) “Best Before” Date on a Prescription Label AB 1458 (Davis) Drugs: Adverse Effects Reporting SB 26 (Simitian) Home-Generated Pharmaceutical Waste SB 43 (Alquist) Cultural and Linguistic Competency SB 238 (Calderon) Medical Information SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus SB 484 (Wright) Ephedrine Products to Schedule V SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews SB 762 (Aanestad) Professions and Vocations; Healing Arts AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHDPD) SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus SB 484 (Wright) Ephedrine Products to Schedule V SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>1st Qtr 09/10: Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>2nd Qtr 09/10: Governor signs SB 819 (Omnibus) Governor vetoes SB 820 (Omnibus) Governor signs SB 821 (Omnibus) Governor signs SB 470 (Corbett) - “Purpose” Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset Governor signs AB 931 (Fletcher) - Emergency Supplies Container Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia</p>
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3rd Qtr 09/10: *Board considers new legislation*

1. *Board of Pharmacy*
 - AB 2104 (Hayashi) – California State Board of Pharmacy
 - SB 1390 (Corbett) – Prescription Container Labels
2. *Pharmacy Practice*
 - AB 1869 (Anderson) – Pharmacy (spot bill)
 - AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors
3. *Sunset Review and Legislative Oversight Proposals*
 - AB 1659 (Huber) – State Government, Agency Repeals
 - AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection
 - SB 954 (Harmon) – Legislative Procedure, Committee Referrals
 - SB 1171 (Negrete McLeod) – Regulatory Boards, Operations
 - SB 1172 (Negrete McLeod) – Sunset of Diversion Program
4. *Regulation of Dangerous Drugs and Devices*
 - AB 1455 (Hill) -- Pseudoephedrine
 - AB 2548 (Block) – CURES – Prescription Drug Monitoring Program
 - SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products
 - SB 1071 (DeSaulnier) – CURES
 - SB 1106 (Yee) – Prescribers – Dispensing of Samples
5. *Pharmacy Licensing Issues*
 - AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies
 - AB 2292 (Lowenthal) – Pharmacy: Clinics
 - AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program
6. *Distribution of Needles and Syringes*
 - AB 1701 (Chesbro) – Hypodermic Needles and Syringes
 - AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services
 - AB 2139 (Chesbro) – Solid Waste: Product Stewardship
 - SB 1029 (Yee) -- Hypodermic Needles and Syringes
7. *General / Other*
 - AB 2112 (Monning) – Prescription Record Privacy Act

	<p>4th Qtr 09/10: Board considers additional legislation AB 1939 (Fletcher) Sharps Waste SB1111 (Negrete McLeod) DCA Enforcement Model</p> <p>Apr. 2010: Board takes positions on legislative measures: AB 1701 (Chesbro) Support AB 2104 (Hayashi) Oppose AB 2292 (Lowenthal) Support SB 1106 (Yee) Support if Amended AB 1916 (Davis) Bill is dead (failed deadline) AB 2112 (Monning) Bill is dead (failed deadline) SB 1111 (Negrete McLeod) Bill is dead (failed deadline)</p> <p>May 2010: AB 1869 (Anderson) Bill is dead (failed deadline) AB 1939 (Fletcher) Bill is dead (failed deadline)</p> <p>June 2010: SB 1390 (Corbett) Fails passage in policy committee SB 954 (Harman) Bill is dead (failed deadline) SB 1171 (Negrete McLeod) Bill is dead (failed deadline) AB 2139 (Chesbro) Bill is dead (failed deadline) AB 2292 (Lowenthal) Bill is dead (failed deadline) AB 2548 (Block) Bill is dead (Failed deadline)</p> <p>Apr./May 2010: AB 2104 (Hayashi) Amended twice</p> <p>June 2010: AB 2104 (Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.</p> <p>July 2010: AB 2077 (Solorio – Centralized Hospital Packaging Pharmacies. Board establishes Support position.</p>
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1st Qtr 10/11: Governor signs the following legislation:

AB 2104 (Hayashi) – Requires DCA Director approval of the Board's appointment of Executive Officer (Chapter 374, Statutes of 2010)

AB 1659 (Huber) – State Government, Agency Repeals (Chapter 666, Statutes of 2010)

AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection (Chapter 670, Statutes of 2010)

SB 1172 (Negrete McLeod) – Diversion Programs (Chapter 517, Statutes of 2010)

AB 1071 (Chesbro) – Hypodermic Needles and Syringes (Chapter 667, Statutes of 2010)

SB 1414 (Hill) – Apomorphine: Unscheduled (Chapter 76, Statutes of 2010)

AB 2699 (Bass) – Licensure Exemption: State of Emergency (Chapter 270, Statutes of 2010)

Governor vetoes the following legislation:

AB 1858 (Blumenfield) – Hypodermic Needles and Syringes

SB 1029 (Yee) – Hypodermic Needles and Syringes

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

AB 2747 (Lowenthal) – Prisons: Pharmacy Services

The following legislation fails passage:

AB 1455 (Hill) – Pseudoephedrine

SB 1071 (DeSaulnier) – CURES

SB 1106 (Yee) – Prescribers Dispensing of Samples

AB 2551 (Hernandez) – Pharmacy Technician Scholarship & Loan Repayment Program

AB 1310 (Hernandez) – Healing Arts Database

2nd Qtr 10/11: SB 41 (Yee) Introduced – Hypodermic Needles and Syringes

AB 36 (Hill) Introduced – Ephedrine: Retail Sale

Board approves provisions for sponsorship in 2011/2012 Session:

(1) Pharmacists Recovery Program

- Section 4362 – Amend to require that a participant in the pharmacists recovery program be responsible to pay an administrative co-pay each month to cover a portion of the administrative costs borne by the board; provision to allow the board to waive or defer the requirement based on a demonstrated financial hardship.*

3rd Qtr 10/11: Board advised changes to 4362 will not be sought this year.

1. Board-Sponsored Legislation

SB 431 (Emmerson) Pharmacies: regulation

- Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors
- Sections 4104, 4105 and 4112 – Enforcement Enhancements

2. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

a. Board of Pharmacy/Licensing

- AB 377 (Solorio) Pharmacy: Centralized hospital packaging
- AB 399 (Lowenthal, Bonnie) Corrections: offender pharmacies
- AB 847 (Lowenthal, Bonnie) Pharmacy: clinics
- SB 100 (Price) Healing arts
- SB 632 (Emmerson) Pharmacy

b. Controlled Substances/Marijuana

- AB 507 (Hayashi) Pain management
- SB 847 (Correa) Medical Cannabis Licensing Act
- SB 786 (Dutton) Controlled substances

c. Reporting Requirements/Records

- SB 260 (Cannella) Controlled substances
- SB 315 (Wright) Ephedrine and pseudoephedrine
- SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System

d. Healing Arts/DCA

- AB 675 (Hagman) Continuing education
- AB 958 (Berryhill) Regulatory boards: limitation periods
- AB 1003 (Smyth) Professional and vocational licenses
- AB 1328 (Pan) Professions and vocations
- SB 231 (Emmerson) Regulatory boards: healing arts
- SB 227 (Wyland) Business and professions: licensure (corrected)
- SB 538 (Price) Healing arts
- SB 544 (Price) Healing arts
- SB 667 (Wyland) Healing arts

e. Other

- AB 389 (Mitchell) Bleeding disorders: blood clotting products
- AB 604 (Skinner) Needle exchange programs
- SB 41 (Yee) Hypodermic Needles and Syringes
- SB 514 (Simitian) Dextromethorphan: sale to minors prohibited
- SB 850 (Leno) Medical records: confidential information

4th Qtr 10/11: Board considers and establishes positions on the following legislation

- a. Board of Pharmacy/Licensing
 - AB 377 (Solorio) Pharmacy: Centralized hospital packaging - Support if amended
 - AB 399 (Lowenthal, Bonnie) Corrections: offender pharmacies -Support
- b. Controlled Substances/Marijuana
 - AB 507 (Hayashi) Pain management - Oppose
- c. Reporting Requirements/Records
 - SB 315 (Wright) Ephedrine and pseudoephedrine - Support
 - SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System - Watch
 - AB 1280 (Hill) Ephedrine Sales - Watch
- d. Healing Arts/DCA
 - SB 541 (Price) Expert Consultants - Support
- e. Other
 - AB 389 (Mitchell) Bleeding disorders: blood clotting products - Watch
 - AB 604 (Skinner) Needle exchange programs - Support
 - SB 41 (Yee) Hypodermic Needles and Syringes - Support if amended
 - SB 514 (Simitian) Dextromethorphan: sale to minors prohibited - Support

1st Qtr 11/12: Board considers and changes positions in the following legislation

- a. Controlled Substances/Marijuana
 - AB 507 (Hayashi) Pain management - Watch
 - AB 389 (Mitchell) Bleeding disorders: blood clotting products - Oppose

Governor signs the following legislation

- SB 541 (Price) Expert Consultants
(Chapter 339, Statutes of 2011)

2nd Qtr 11/12: Governor signs the following legislation

- AB 507 (Hayashi) Pain management
(Chapter 396, Statutes of 2011)
- SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System (Chapter 418, Statutes of 2011)
- SB 514 (Simitian) Dextromethorphan: sale to minors prohibited
(Chapter 199, Statutes of 2011)
- SB 431 (Emmerson) Pharmacies (Chapter 646, Statutes of 2011)
- SB 850 (Leno) Medical records: confidential information
(Chapter 714, Statutes of 2011)

Governor signs the following legislation

- AB 604 (Skinner) Needle exchange programs
(Chapter 744, Statutes of 2011)
- SB 41 (Yee) Hypodermic Needles and Syringes
(Chapter 738, Statutes of 2011)

3rd Qtr 11/12: AB 1442 (Wieckowski) introduced. Pharmaceutical Waste

	<p>7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.</p> <p><i>March 2007: Licensing Committee considers and approves concept. More work is required.</i></p> <p><i>June 2007: Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.</i></p> <p><i>Sept. 2007: Licensing Committee forwards to full board legislative proposal.</i></p> <p><i>Oct. 2007: Board approved draft legislation.</i></p> <p><i>Nov. 2007: Staff meeting with stakeholders to elicit support for the proposal.</i></p> <p><i>Dec. 2007: Staff develop fact sheets and work with experts in immunizations.</i></p> <p><i>Feb. 2009: Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.</i></p> <p><i>April 2009: Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.</i></p> <p><i>May 2009: Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)</i></p> <p><i>Jan. 2010: Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.</i></p> <p><i>Jan. 2010: AB 977 passes out of Assembly Health Committee</i></p> <p><i>Board reaffirms "support" position.</i></p> <p><i>April 2010: Board changes position from "sponsor" to "support".</i></p> <p><i>June 2010: AB 977 amended to apply only to a pharmacist associated with an independent community pharmacy. Bill died in committee.</i></p>
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	<p>8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.</p> <p><i>Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.</i></p> <p><i>Apr. 2008: First public forum held in Fremont.</i></p> <p><i>May 2008: Staff develop survey form to distribute to consumers to solicit input</i> <i>Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.</i></p> <p><i>June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.</i></p> <p><i>July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.</i></p> <p><i>Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.</i> <i>Public Education Committee updated on the status of survey results.</i></p> <p><i>Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.</i></p> <p><i>May 2009: Bill passes out of the Senate</i></p> <p><i>Oct. 2009: Governor signs SB 470 (Chapter 590, Statutes of 2009).</i></p> <p><i>Oct. 2009: Board approves regulatory language for notice.</i></p> <p><i>Nov. 2009: Regulatory effort initiated.</i></p> <p><i>June 2010: Board adopts final text (See Objective 3.2, Task 16).</i></p> <p><i>Nov. 2010: Office of Administrative Law approves regulation.</i></p> <p><i>Jan. 2011: Regulation takes effect.</i></p> <p>9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.</p> <p><i>Dec. 2008: Board receives findings of independent fee audit.</i></p> <p><i>Jan. 2009: Board votes to pursue fee increase.</i></p> <p><i>Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.</i></p> <p><i>June 2009: Bill passes out of the Assembly.</i></p> <p><i>Sept. 2009: Bill is enrolled and sent to the Governor.</i></p> <p><i>Sept. 2009: Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.</i></p> <p><i>Oct. 2009: Governor signs AB 1071 (Chapter 270, Statutes of 2009)</i></p> <p><i>Jan. 2010: Statutory fee schedule implemented (supersedes 16 CCR 1749)</i></p>
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10. Advocate legislation to enhance the board's enforcement activities.

Jan. 2010: *Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):*

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory.

Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.

Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

2nd Qtr 10/11: *Board approves provisions for sponsorship in 2011/2012 Session.*

(1) Enforcement Enhancements

- *Section 4104 – Amend to clarify that a pharmacy shall provide to the board, within 14 days, evidence of a licensee's theft or impairment. Require the pharmacy to conduct an audit to determine the scope of loss, and to provide the board with a certified copy of the audit results.*
- *Section 4105 – Amend to specify a time period in which records shall be provided to the board when requested by an inspector or authorized representative of the board.*
- *Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation.*

(2) Pharmaceutical Waste – Reverse Distributors

- *Section 4040.5 – Amend to specify that a reverse distributor may not accept previously dispensed medicine and specify that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler.*
- *Section 4081 – Amend to specify what records must be maintained of drugs being returned to a wholesaler or reverse distributor; and specify information that is to be maintained for drugs that are returned via a licensed integrated waste hauler.*
- *Section 4126.5 – Amend to authorize a pharmacy to furnish drugs to a licensed integrated waste hauler for the sole purpose of disposing of pharmaceutical waste returned to a pharmacy.*

3rd Qtr 10/11: *SB 431 is introduced containing – amendments to 4104, 4105, and 4112.*

4th Qtr 10/11: *SB 431 amended to also contain changes to 4081, 4126.5, and 4126.7.*

2nd Qtr 11/12: *Governor signs SB 431 (Chapter 646, Statutes of 2011).*

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> <p>1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (§ 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i></p> <p>2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (§ 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i></p> <p>3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i></p> <p>4. Repeal the requirement to post a notice regarding electronic files (§ 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i></p> <p>5. Revise and update Disciplinary Guidelines (§ 1760). <i>Oct. 2007: Board approves regulation for 45-day comment period.</i> <i>May 2009: Regulation and revised Disciplinary Guidelines approved and takes effect.</i> <i>July 2011: Discussion to update Disciplinary Guidelines to also incorporate recommendations of the Substance Abuse Coordination Committee.</i> <i>Sep. 2011: Board approves draft regulation text and Disciplinary Guidelines for 45-day public comment.</i> <i>Oct. 2011: Board releases regulation text for 45-day comment to update the regulation and the Disciplinary Guidelines incorporated by reference. Regulation Hearing scheduled for January 31, 2012.</i></p> <p>6. Self-assessment of a wholesaler by the designated representative (§ 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <i>March 2011: Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-26 (See Objective 3.2, Task 25)</i></p> <p>7. Exempt the address of records of interns from display on the board's Website (§ 1727.1). <i>Sep. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i></p> <p>8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i></p>

9. **Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(§ 1707.2).**
Feb. 2007: Board notices regulation for 45 days comment period.
Nov. 2007: Regulation changes takes effect.
Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.
1st Qtr 10/11: Board discusses updates to Notices to Consumers (See Objective 3.2, Task 19)
10. **Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.**
Dec. 2007: Office of Administrative Law approves Section 100 Changes.
Amend the following:
1707 – Waiver of requirements for off-site storage of records
1709.1 – Designation of pharmacist-in-charge
1715 – Self-assessment of a pharmacy by the pharmacist-in-charge
1717 – Pharmacy practice
1746 – Emergency contraception
1780.1 – Minimum standards for veterinary food-animal drug retailers
1781 – Exemption certificate
1787 – Authorization to distribute dialysis drugs and devices
1790 – Assembling and packaging
1793.8 – Technician check technician
Repeal section 1786 – Exemptions
March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.
11. **Increase fees to keep the board's contingency fund solvent and maintain operations.**
Nov. 2007: Office of Administrative Law approves rulemaking.
Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.
Jan. 1, 2008: New fees take effect.
Oct. 2009: Governor signs AB 1071, new fee schedule.
Jan. 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)
12. **Secure regulatory standards for pharmacies that compound. (§1735 et al)**
Nov. 2007: Board releases language for the 45-day comment period.
Sep. 2008: Board releases (withdrawn) language for 45-day comment period.
Oct. 2008: Regulation hearing
Jan. 2010: Office of Administrative Law approves regulation.
July 2010: Regulation and Self-Assessment Form 17M-39 is effective.
Board staff developing fact sheet for pharmacies.
March 2011: Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-39 (See Objective 3.2, Task 24)
Board notices regulation for 45-day comment period to update § 1735.2 and § 1751 and to revise/update the Compounding Self-Assessment form (17M-39).
4th Qtr 10/11: Board motions to adopt regulation.
Rulemaking submitted to the Department for review.
1st Qtr 11/12: Office of Administrative Law approves Rulemaking
Regulation takes effect October 19, 2011
13. **Establish an ethics course (§1773 and §1773.5).**
Sep. 2008: Board notices regulation for 45-day comment period.
Sep. 2009: Regulation takes effect.

14. **Pharmacist Renewal Requirements (§1702).**
Dec. 2009: Board notices regulation for 45-day comment period.
Feb. 2010: Board adopts regulation.
June 2010: Office of Administrative Law approves regulation.
Dec. 2011: Regulation takes effect.
15. **Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions (§1721 and §1723.1).**
Oct. 2009: Board notices regulation for 45-day comment period.
Jan. 2010: Board adoption of regulation as noticed.
July 2010: Rulemaking submitted to the Office of Administrative Law for review.
Aug. 2010: Office of Administrative Law approves regulation.
Sep. 2010: Regulation takes effect.
16. **Standardized, Patient-Centered Prescription Labels (§1707.5)**
Nov. 2009: Board notices regulation for 45-day comment period.
Jan. 2010: Regulation hearing.
Feb. 2010: Board modifies text of regulation.
Board notices modified text for 1st 15-day comment period.
Apr. 2010: Board modifies text of regulation.
Board notices modified text for 2nd 15-day comment period.
June 2010: Board adopts regulation language noticed on April 28.
July 2010: Rulemaking submitted to Department for review.
Oct. 2010: Rulemaking submitted to the Office of Administrative Law for review.
Nov. 2010: Office of Administrative Law approves rulemaking.
Jan. 2011: Regulation takes effect.
1st Qtr 11/12: Communication and Public Ed Comm. discusses existing requirements
3rd Qtr 11/12: Communication and Public Ed Comm. discusses existing requirements
17. **Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746)**
Jan. 2010: Board approves language to initiate rulemaking to correct a typographical error in the Emergency Contraception Protocol regulation.
July 2010: Board begins working with Medical Board to update the EC Protocol.
May-June 2011: Executive Officer works with Medical Board (MBC) and others to revise the protocol. The MBC will discuss at its July 2011 meeting. Pharmacy will discuss update of board regulation after MBC approval. The board will also need to update the Patient Information Fact Sheet on EC Protocol.
2nd Qtr 11/12: Medical Board of California approves draft regulation text
3rd Qtr 11/12: Board Notices regulation for 45-day comment period.
18. **Board Issued Continuing Education (CE) Credit (§1732.2)**
Feb. 2010: Board votes to amend section 1732.2 defining board-issued CE and notice regulation for 45-day comment period.
Oct. 2010: Board notices regulation for 45-day comment period.
Feb. 2011: Board issues modified text for 15-day comment period.
2nd Qtr 11/12: Board adopts and completes rulemaking and submits the file for administrative review.
Director of DCA extends one-year filing period per B&PC 313.1(e)(1)
Final Regulation to Office of Administrative Law for review (12/28/11)

19. Notice to Consumers re: Patient-Centered Prescription Labels

Apr. 2010: Board directs staff to bring regulatory language to the July 2010 meeting re: increased font size, and language services.

July 2010: Board discusses possible language for Notice to Consumers.

Oct. 2010: Board discusses possible language for Notices to Consumers. Votes to modify and move existing Consumer Notices from §1707.2 to a new section at 16 CCR §1707.6, to include language for increased font size and oral interpretive services, and other changes.

1st - 3rd Qtr 10/11: Board discusses updates to the Notices to Consumers to incorporate Patient-Centered Requirements.

3rd Qtr 10/11: Board approves language to amend 16 CCR 1707.2 and to add 16 CCR §1707.6; for 45-day comment period and schedules regulation hearing for July 2011.

4th Qtr 10/11: Board notices regulation for 45-day comment period and notices regulation hearing for July 27, 2011.

1st Qtr 11/12: Board conducts Regulation Hearing
Board revises text and releases modified text for 15-day public comment.
Absent negative comments, directs Executive Officer to adopt and complete rulemaking.

2nd Qtr 11/12: Executive Officer adopts regulation and submits rulemaking for Administrative Review.
Rulemaking filed with Office of Administrative Law for review.
Rulemaking withdrawn from OAL to secure Department of Finance approval of Std. 399.

3rd Qtr 11/12: Rulemaking resubmitted to OAL for review. OAL approves rulemaking.
Regulation takes effect February 16, 2012.
Office of Administrative Law approves Rulemaking
Regulation effective 2/16/2012

20. Update references to USP Standards (§1780)

1st Qtr 07/08: Board considers review of USP references.

2nd Qtr 07/08: Subcommittee established to conduct full review of USP updates needed.

21. Veterinarian Food-Animal Drug Retailer Self-Assessment (§1785)

1st Qtr 07/08: Board approves regulation for notice.

2nd Qtr 07/08: Work on rulemaking stopped to allow for comprehensive review of Veterinary Food-Animal Drug Retailer Program.

22. Accreditation Agencies for Pharmacies that Compound (§1751.x)

1st Qtr 07/08: Board approves regulation text for notice (upon additional review by counsel, modification of language is necessary prior to notice of proposed text)

- 23. Pharmacist and Intern Pharmacist Applicants to submit a Self-Query from the National Practitioner Data Bank-Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) (§ 1727.2, 1728)**
- 1st Qtr 10/11: Board approves additional modifications to the Pharmacy Technician Application (Form 17A 5) and directs that the language approved in October 2010 and the application approved February 2011 be issued for a 45-day public comment period.*
- 2nd Qtr 10/11: Board votes to require applicants to submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB), and to amend/update the Pharmacy Technician application:*
- Section 1728 – Amend to require an applicant for the pharmacist examination to submit a Self-Query Report from NPDB-HIPDB.*
 - Section 1727.2. – Add new section to require an applicant for an Intern Pharmacist license to submit a Self-Query Report from NPDB-HIPDB.*
 - Section 1793.5. – Amend to require a Pharmacy Technician applicant to submit a Self-Query Report from NPDB-HIPDB; and to modify the Pharmacist Technician Application (17A-5), incorporated by reference.*
- April 2011: Proposed Text to Amend §1793.5 and modify Form 17A-5 issued for 45 day public comment.*
- Oct. 2011: Board votes to require applicants to submit a Self-Query from the NPDB HIPDB.*
- May 2011: Board notices regulation for 45-day comment period.*
- 24. Pharmacy Technician Applicants to submit a Self-Query from the National Practitioner Data Bank-Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) and Revise Pharmacy Technician Application (§ 1793.5)**
- Oct. 2011: Board votes to require applicants to submit a Self-Query from the NPDB HIPDB and to amend/update the Pharmacy Technician Application (17A-5)*
- Feb. 2011: Board approves additional modifications to TCH application.*
- April 2011: Board notices regulation for 45-day comment period.*
- June 2011: Regulation adopted.*
- Rulemaking submitted to the Department for review.*
- 25. Update of Self-Assessment Forms**
- March 2011: Board notices regulation for 45-day public comment period to update 16 CCR §1715, §1735.2, §1751 and §1784 and the self assessment forms incorporated by reference:*
- 17M-13 Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment*
- 17M-14 Hospital Pharmacy Self-Assessment*
- 17M-26 Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment*
- 17M-39 Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment*
- May 2011: Board approves rulemaking.*
- June 2011: Rulemaking submitted to the Department for review.*
- 26. Partial Filling of Schedule II Prescriptions**
- 2nd Qtr 10/11: Board approves language to initiate rulemaking to amend 16 CCR 1745 regarding record keeping requirements for partial fill of a Schedule II prescription.*

	<p>27. Activities that Constitute Unprofessional Conduct [CPEI] (Add § 1762) <i>2nd Qtr 10/11: Board considers language and refers back to the Enforcement Committee</i> <i>Enforcement Committee discusses draft language and makes</i> <i>recommendation to the Board.</i> <i>3rd Qtr 10/11: Board approves language to add 16 CCR § 1762 and directs staff to initiate</i> <i>rulemaking.</i></p> <p>28. Application Review and Criteria for Rehabilitation [CPEI] (Amend § 1769) <i>2nd Qtr 10/11: Board approves amendments to § 1769 and directs staff to initiate a</i> <i>rulemaking</i></p>

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked <p><i>Sept. 2008:</i> Governor vetoes SB 1779.</p> <p><i>Jan. 2009:</i> Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</p> <p><i>Sept. 2009:</i> SB 819 and SB 821 enrolled and sent to the Governor.</p> <p><i>Oct. 2009:</i> Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</p> <p>2. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746)</p> <p><i>July 2010:</i> Board begins working with the Medical Board to update the EC Protocol.</p> <p>3. Initiate review of Pharmacist-in-Charge Requirements.</p> <p>4. Review of Continuing Education for Pharmacists in Specific Areas.</p> <p><i>1st Qtr 10/11:</i> Board moves to pursue implementation of CE for specific content areas.</p>